REMARKS

Claims 1-17 are pending in the application and were subject to a Restriction Requirement. Applicants hereby affirm the election of Group II, claims 12-17, which was made without traverse in a telephone conversation between the Examiner and the undersigned on July 12, 2004. Claims 1-11 have been withdrawn from consideration, pursuant to the Restriction Requirement. Each of the issues raised in the Office Action are addressed as follows.

Priority

The Examiner has concluded that December 16, 2003 should be considered as the priority date for the present claims, stating "the priority document does not show the administration of *Clostridium* toxin to a patient." Applicants respectfully disagree with this conclusion, as the concept of active immunization (in this case, administration of a clostridial toxin or toxoid to a patient) is clearly set forth in earlier priority applications, as is described below.

In applicants' first priority application, U.S. Serial No. 60/062,522, filed October 20, 1997, it is stated on page 4, lines 10-13, that "[t]he invention also provides methods of preventing or treating intestinal clostridial disease in a human patient, which involve percutaneously administering a clostridial (*e.g.*, *C. difficile*) toxin or toxoid to the patient, in the presence or absence of an adjuvant, such as alum." Further, on page 8, lines 19-23, the specification states "[t]he methods include passive and active immunization approaches, which involve percutaneous (*e.g.*, intramuscular, intravenous, or intraperitoneal) administration of antibodies (*e.g.*, polyclonal immune globulin) to *C. difficile* toxoids, *C. difficile* toxoids themselves, or combinations thereof." In addition, on page 9, lines 4-7, it is stated "[t]he

prophylactic and therapeutic methods of the invention involve vaccination with *C. difficile* toxoids, whether in carrying out the treatment itself or in the production of *C. difficile* immune globulin for subsequent use in passive immunization." Further, preparation and administration of vaccine compositions including *C. difficile* toxoids for use in active immunization methods is described in detail on page 9, line 7 through page 10, line 19. The results of experiments showing active immunization according to the invention are described on page 24, line 1 through page 27, line 20. Thus, as it is clear that priority application serial number 60/062,522, filed October 20, 1997, describes active immunization methods, applicants should be entitled to the October 20, 1997 priority date for their claims to such methods.

Information Disclosure Statement

The Examiner notes that certain of the documents listed on the Form PTO 1449 that was filed in this case on January 23, 2004 have not been considered, as copies of the documents were not found in either of the parent applications. Applicants thus submit herewith copies of the documents indicated to be missing.

Rejection under 35 U.S.C. § 102(b)

Claims 12-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kotloff et al., Infection and Immunity 69(2):988-998, 2001. As is explained in detail above, the present claims, which are drawn to active immunization methods, are supported in applicants' priority application, U.S. Serial No. 60/062,522, filed October 20, 1997. This rejection is therefore moot, as the Kotloff document is not prior art to the present claims.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: January 20, 2005

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